Optimizing the Management of Rotator Cuff Problems

Review Change Summary, Review Comments and AAOS Responses

Peer Review:
May 26, 2010 – June 30, 2010

Public Comment:
August 30, 2010 – September 30, 2010
Change Summary

1
Changes Made to the Confidential Draft of the
Guideline on Optimizing the Management of Rotator Cuff Problems

Peer Review
May 26, 2010 – June 30, 2010

Public Comment
August 30, 2010 – September 30, 2010

LINE 29
The following text has been bolded for emphasis:

All readers of this summary are strongly urged to consult the full guideline and evidence report for this information.

LINE 541
Text was added for clarification (bolded).

This clinical practice guideline is based on a systematic review of published studies on the treatment of rotator cuff problems in adults (>19 years).

LINE 565
We have removed the words “all qualified” from the sentence.

LINE 570, INTENDED USERS
Additional text was added for clarification:

“Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians, physician assistants and other healthcare professionals who routinely see this type of patient in various practice settings may also find this guideline useful.”

LINE 611
Footnote references have been removed and added to reference list for clarity.

LINE 663
This paragraph was edited to read as follows:

From:
The resulting draft guidelines were peer-reviewed, sent for public commentary, and then sequentially approved by the AAOS Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (see for a description of the AAOS bodies involved in the approval process).

To:

The resulting draft guidelines are then peer-reviewed, edited in response to that review, and then sent for public commentary whereafter additional edits are made. Thereafter, the draft guideline is sequentially sent for approval by the AAOS Evidence Based Practice Committee, AAOS Guidelines and Technology Oversight Committee, AAOS Council on Research, Quality Assessment, and Technology, and the AAOS Board of Directors (see for a description of the AAOS bodies involved in the approval process). All AAOS guidelines are reviewed and updated or retired every five years in accordance with the criteria of the National Guideline Clearinghouse.

**LINE 765**
Text was added for clarification:

*We did not include systematic reviews compiled by others or guidelines developed by other organizations. These documents are developed using different inclusion criteria than those specified by the AAOS work group. Therefore they may include studies that do not meet our inclusion criteria. We recalled these documents, if the abstract suggested they might provide an answer to one of our recommendations, and searched their bibliographies for additional studies to supplement our systematic review.*

**LINE 776**
Additional text was added (bolded):

*The study attrition diagram in Appendix IV provides details about the inclusion and exclusion of these studies. A total of seventy-four studies met the inclusion criteria for this guideline; fifteen of these studies answered at least two of the recommendations.*

**LINE 916, REVISION PLANS**
This text has been edited:

From:

*This guideline represents a cross-sectional view of current treatment and will become outdated when more sophisticated tests, more objective assessments, and more rigorous differential diagnoses are possible. Because of the aging population, changing medical reimbursement practices by many payors, and the high level of interest in this topic, the guideline will be revised in accordance with changing practice, emerging treatment options, new technology, and new evidence. This guideline will be considered for revision in 2015.*

To:
This guideline represents a cross-sectional view of current treatment and will become outdated when more sophisticated tests, more objective assessments, and more rigorous differential diagnoses are possible. All AAOS guidelines are updated or retired after five years, in accordance with the criteria of the National Guideline Clearinghouse.

**LINE 963**
We have edited the Level of Evidence for Recommendation 2 from III\IV to IV based on the body evidence.

**LINE 968**
Additional text was added (bolded):

*Our systematic review identified one Level III study\(^23\) that compared conservative to surgical treatment of rotator cuff tears. In this study, sixty patients treated without surgery were compared to seventy-seven with rotator cuff repair. *Per this study, in group A, tears were non-traumatic in 73% of cases and traumatic in 27% of cases. In group B, tears were non-traumatic in 32% of cases and traumatic in 68% of cases.* Statistically significant less pain on shoulder range of motion and at night was seen in those patients who had surgery as compared to those with conservative treatment. Eighty-one percent of the surgical patients reported excellent results as compared to thirty-seven percent with conservative treatment although the authors did not report statistical significance in this comparison. Because there was only one Level III study to support this recommendation, we also examined Level IV articles.*

**LINE 993**
All Recommendations with evidence had text added summarizing the applicable tables and figures as indicated in Recommendation 2:

**SUPPORTING EVIDENCE- SURGICAL VERSUS CONSERVATIVE TREATMENT:**
Tables relevant to this recommendation are: Table 6
Figures relevant to this recommendation are: Figure 1 through Figure 3

**LINE 1341**
**RATIONALE FOR 4A**
Text was added for additional clarification (bolded):

*Several Level II studies\(^{59, 60, 23}\) report the beneficial effects of exercise in decreasing pain and improving function in patients with rotator cuff related symptoms without a full-thickness tear. One study\(^{23}\) reported on 24 patients undergoing an exercise program and noted significantly improved pain scores on the VAS [visual analog scale] after 8 weeks of treatment; *post hoc pairwise comparisons of the two groups in this study showed significantly more improvement in the exercise plus manual therapy group using a composite pain measure.* Another study\(^{59}\) reported patients had significant improvements in pain at rest, pain at night and Constant-Murley scores after 3 months of a home exercise program. A third study\(^{60}\) randomized patients between a group undergoing
exercise and a control group. The group undergoing exercise had statistically significant improvements in pain levels at rest, pain with movement and upper extremity function (DASH-Laborers subscale). No statistically significant difference was reported in patients who participated in supervised and unsupervised exercises.

LINE 1574
We have edited the Level of Evidence for Recommendation 4B from I-II to II based on the body evidence.

LINE 1948
Additional text was added for clarification:

Two additional studies\(^{73, 74}\) addressed repair of traumatic anterior superior rotator cuff tears with combined subscapularis and supraspinatus tears. One study reported on thirty patients with a traumatic tear who had open repair at an average of 4.5 months after injury and the other reported on twenty four patients of which twenty-two recalled a specific incident at which the injury occurred. (See Table 26 for the summary of these results.) One study reported there were no significant correlations between outcome and a number of preoperative factors including duration of symptoms.

LINE 1954
We have edited this line from:

Physical examination findings including supraspinatus and infraspinatus muscle atrophy as well as internal and external rotation lag signs can be indicative of larger and more chronic rotator cuff tears.

To:

Physical examination findings including supraspinatus and infraspinatus muscle atrophy as well as internal and external rotation lag signs may be indicative of larger and more chronic rotator cuff tears.

LINE 3215
We have edited the Level of Evidence for Recommendation 10C from II-III to III based on the body evidence.

LINE 3391-3395
Additional text was added for clarification (bolded):

“After a systematic search, no clinical data was found supporting or refuting a negative or positive effect of range of motion exercises (passive, active or active assisted) for post-operative rehabilitation after repair of a full thickness rotator cuff tear on tendon healing or outcomes after rotator cuff repair. Therefore, the work group could not recommend for or against the timing of range of motion exercises in the post-operative period.”
REFERENCE LIST OF INCLUDED ARTICLES

An error in our reference manager program that creates and formats our bibliographies was detected. The list of cited references in the guideline was incorrect. It is now corrected and all references are listed. In addition, we have added a sentence to the guideline at line 814 stating the following:

“A total of seventy-five studies met the inclusion criteria for this guideline; fifteen of these studies answered at least two of the recommendations.”
ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:
- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:

Name of Reviewer__Rolando Izquierdo MD_______________________________________
Address___750 E Terra Cotta Suite C______________________________________________
City__Crystal Lake______________________ State_____IL____________ Zip Code___60014________
Phone ____815-455-0800______Fax ____815-455-2895_____E-mail__rizquierdo@crystallakeortho.com_____________________
Specialty Area/Discipline: ___Shoulder____________________________________
Work setting: ____Private Practice___________________Credentials: ______________________

May we list you as a Peer Reviewer in the final Guidelines (GL)?

x☐ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society?
☐ Yes x☐ No

If yes, may we list your society as a reviewer of this guideline?
☐ Yes ☐ No

Society Name: ___________________________________________
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

If the boxes below are not checked and/or the reviewer does not attach his/her conflicts of interest, the reviewer’s comments will not be addressed by the AAOS nor will the reviewer’s name or society be listed as a reviewer of this GL. If a committee reviews the guideline, only the chairperson/or lead of the review must declare their relevant COI.

☐ I have declared my conflicts of interest on page 2 of this form.

x☐ I have declared my conflicts of interest in the AAOS database; my customer # is XXXXXX_

☐ I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.
### REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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<tr>
<th>Question</th>
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<td>Do you or a member of your immediate family receive royalties for any pharmaceutical, biomaterial or orthopaedic product or device?</td>
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Review Instructions
Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments in WORD format by end of day June 30, 2010.

Please indicate your level of agreement with each of the following statements by placing an “X” in the appropriate box.

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<th>Statement</th>
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I would like to congratulate the work group on completing a very arduous task. Much like other guidelines one of the hidden gifts of this exercise is to identify future areas of research, and I encourage the panel to help organize meaningful trials to answer some of the questions that remain regarding the management of rotator cuff disease.

Thank you.

The first recommendation is a consensus decision without sufficient literature to support it. “In the absence of reliable evidence, it is the opinion of the work group that surgery not be performed for asymptomatic, full thickness rotator cuff tears.” I agree with the recommendation, however, I would like to know what the work group considers “asymptomatic”. Is there a certain point on the VAS pain score that qualifies as "symptomatic"? Is there a certain score on a validated scoring tool that qualifies as "symptomatic"? How can we make a consensus recommendation for treatment without defining asymptomatic and symptomatic rotator cuff tears?

For recommendations supported by evidence, we define the terms as given by the author(s) of the supporting evidence. In this case, no evidence exists and the recommendation is based on consensus. The work group defines asymptomatic patients as "patients without symptoms." Admittedly, these are patients who are not likely to seek medical help or advice until they are symptomatic; however, if an asymptomatic full thickness rotator cuff tear were identified, we would not recommend surgery for those patients until they became symptomatic because the primary indication for rotator cuff repair is significant pain or dysfunction affecting quality of life. Please see the rationale for Recommendation 1, line 954.

The work group discussions did not define “asymptomatic” prior to the literature searches. The physician workgroup and research analysts’ understanding of the term was “a shoulder that did not have pain, weakness or loss of motion that was interfering with quality of life or that the patient felt was significant enough to seek medical attention.”

Ultimately, the decision to treat a patient or evaluate them as an “asymptomatic” patient will be based on the physician’s exam and mutual communication with the given patient. The vice-chair of the work group notes that in the literature “asymptomatic” is defined as: a VAS of less than three or duration of symptoms less than 6 wks (all people will experience transient shoulder soreness at some point) or any pain not requiring medication or medical attention. The AAOS disclaimer states that "Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient and physician.”

The second recommendation “Rotator cuff repair is an option for patients with chronic, symptomatic full thickness tears.” I was wondering if the work group considered making the results of rotator cuff
repair and the effects of muscle atrophy and fatty infiltration on outcomes separate recommendations. Would the results for this recommendation be different if we divided this into two separate topics? First, “We recommend rotator cuff repair for symptomatic full thickness rotator cuff tears.” Second, “The results for rotator cuff repair are less predictable as muscle atrophy and fatty infiltration increase.” This may change the status of the recommendation.

The status of this recommendation would not change. The body of evidence to support the recommendation is comprised of poor quality evidence. One Level III comparative study and six Level IV studies support this recommendation. Table 4 “Grade of Recommendation Description” defines this evidence as “poor quality evidence.”

The work group did consider these two issues separately. Muscle atrophy and fatty degeneration was considered as prognostic factors and these results are presented in Recommendation 7.

Also, “The results for rotator cuff repair are less predictable as muscle atrophy and fatty infiltration increase” is a statement and does not define an action. A good recommendation takes the form of [What] should be done in [whom], [when], [where] and [how often]. This statement does not consider all of these elements.

In the rationale for the fifth recommendation “Early surgical repair after acute injury is an option for patients with a rotator cuff tear.” the author states “internal and external rotation lag signs can be indicative of larger and more chronic rotator cuff tears”. (Line 1954) This can be a little confusing for the reader since lag signs on physical exam are more directly related to the size of the tear and the specific tendons which are torn rather than the age of the tear.

The work group believes that the chronicity with associated disuse of the arm can lead to more weakness and therefore lag signs. Based on your comments, we have edited Line 1954 to read as:

“Physical examination findings including supraspinatus and infraspinatus muscle atrophy as well as internal and external rotation lag signs may be indicative of larger and more chronic rotator cuff tears.”

Finally, in recommendation twelve the work group consensus is that “In the absence of reliable evidence, it is the opinion of the work group that local cold therapy is beneficial to relieve pain after rotator cuff surgery.” I find it curious that the use of interscalene blocks was not discussed or investigated, and that despite lack of evidence the work group made a consensus recommendation to utilize cold therapy post-operatively. I disagree with their rationale, cold therapy units tend to be very expensive and frequently not covered by third party payors and insurance companies, making them a financial burden on patients.

In recommending local cold therapy, the work group believed the use of intermittent crushed ice and other forms of cryotherapy such as ice packs are options to relieve patient pain. Ice is readily available for most patients and easily applied with or without the use of a “cold therapy unit”, thereby making it assessable and affordable to most patients.

At the introductory meeting, the work group did not ask any recommendations that included or concerned the use of intrascalene blocks. New searches and topics cannot be added to the guideline at this time, but your comments will be considered if and when this guideline is updated. We update
OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

☐ Strongly recommend

☒ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure
American Academy of Orthopaedic Surgeons
[Optimizing the Treatment of Rotator Cuff Problems]
Guidelines Peer Review Form

ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

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• Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
• Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:
Name of Reviewer___Charles Reitman______________________________________
Address___6620 Main Street, 1325____________________________________________
City______Houston__________ State_____TX_______ Zip Code___77030________
Phone _______713-873-4353__________Fax ___________________E-mail__creitman@bcm.tmc.edu______
Specialty Area/Discipline:   Orthopedic Surgery, Spine__________
Work setting: ________Academic________Credentials: ______________________

May we list you as a Peer Reviewer in the final Guidelines (GL)?   X Yes   ☐ No
PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society?   X Yes   ☐ No

If yes, may we list your society as a reviewer of this guideline?   X Yes   ☐ No
Society Name: _____________AAOS___________________
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X I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.

02.10  Rev 3
REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

Charles A Reitman, MD:

Submitted on: 05/31/2010 at 09:19 AM

Item 1. Royalties from a company or supplier
The following conflicts were disclosed

- No Conflict Reported

Item 2. Speakers bureau/paid presentations for a company or supplier
The following conflicts were disclosed

- No Conflict Reported

Item 3A. Paid employee for a company or supplier
The following conflicts were disclosed

- No Conflict Reported

Item 3B. Paid consultant for a company or supplier
The following conflicts were disclosed

- No Conflict Reported

Item 3C. Unpaid consultant for a company or supplier
The following conflicts were disclosed

- No Conflict Reported

Item 4. Stock or stock options in a company or supplier
The following conflicts were disclosed

- No Conflict Reported

Item 5. Research support from a company or supplier as a PI
The following conflicts were disclosed

- No Conflict Reported

Item 6. Other financial or material support from a company or supplier
The following conflicts were disclosed

- No Conflict Reported

Item 7. Royalties, financial or material support from publishers
The following conflicts were disclosed

- No Conflict Reported
Item 8. **Medical/Orthopaedic publications editorial/governing board**
The following conflicts were disclosed

- No Conflict Reported

Item 9. **Board member/committee appointments for a society**
The following conflicts were disclosed

- North American Spine Society
Reviewer Instructions
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Dear Dr. Reitman,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline. We have included responses to both your 2010 comments in the section below and your original 2009 comments. For your reference, your 2009 comments as well as our responses, which are based on the updated draft, may be found at the end of this document following your “overall assessment” of the most recent draft.

This is much improved. Much more objective and consistent.

Dear Dr. Reitman,

We sincerely appreciate the time, effort and expertise you have contributed to this review process. We believe your comments help strengthen the document we ultimately present to the AAOS BOD for approval. Please accept our sincerest Thank-you for your input.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

- [x] Strongly recommend
- [ ] Recommend (with provisions or alterations)
- [ ] Would not recommend
- [ ] Unsure

2009 Original Comments:

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report

1A – Recommendation of I seems more appropriate than C. Not a shred of evidence and likely multiple, dissimilar opinions.

RECOMMENDATION 1A
A course of non-operative treatment is an option for patients diagnosed with an asymptomatic, full thickness rotator cuff tear, understanding that there is a possibility of disease progression and need for further imaging or clinical care. Strength of Recommendation: C

Based on reviewer comments, this recommendation was readdressed by the work group and edited to read as follows:
In the absence of reliable evidence, it is the opinion of the work group that surgery not be performed for asymptomatic, full thickness rotator cuff tears.

Strength of Recommendation: Consensus

1B - Recommendation of I seems more appropriate than C. Not a shred of evidence and likely multiple, dissimilar opinions.

Based on reviewer comments and lack of supporting evidence, the work group readdressed Recommendation 1B and agreed to delete it.

3A – Appears to satisfy Level IV evidence. Would rate this as IV, C.

Recommendation 3a:
Rotator Cuff tears AND exercise
We cannot recommend for or against exercise programs (supervised or unsupervised) for patients with rotator cuff tears.

The evidence for this recommendation is conflicting and lacks generalizability; hence, the work group evaluated the data as inconclusive.

4A - The evidence is not multiple levels. If the level I evidence is solid, this would be a level I recommendation, regardless of the volume of additional lower levels of evidence. In this case, I would consider this overall as level II evidence.

The strength of the recommendation is based on the overall body of evidence. For this recommendation, the level of evidence is based on one Level I and nine Level II studies; therefore, you are correct that the body of evidence is Level II. This correlates to a strength of recommendation that is moderate.

4C – According to the criteria in the appendix, this should be a Grade B.
The evidence for the use of short term corticosteroids is conflicting; hence, in the rewrite the workgroup evaluated the overall body of evidence for this recommendation as inconclusive.

4D - The evidence is not multiple levels. If the level I evidence is solid, this would be a level I recommendation, regardless of the volume of additional lower levels of evidence. In this case, I would consider this overall as level II evidence.

We have edited all instances where this occurred and assigned a level of evidence corresponding to the body of evidence presented and the Strength of the Recommendation.
4F – All these studies were level II by design, but all suffered from significant methodologic flaws which would downgrade their evidence. See lines 657 – 660 for downgrading evidence. This should be reviewed again. These would be downgraded to at least level III, and some even possible to level IV. Depending on how they downgrade the information, this will be either a Level III or IV, Grade I.

See statement above.

5A – Per their review this is not level V data, it is level IV. Grade C is appropriate.

See statement above.

5B – Per their review this is not level V data, it is level IV. Grade C is appropriate. They downgraded level IV to level V because there were no well conducted, randomized studies, but that is no reason to downgrade a level IV study which by definition is not great evidence. These were adequate level IV studies, three of them, and support a level of evidence of IV.

See statement above.

7A – It would seem that there is some low level evidence for this recommendation, although conclusions are contradictory. Thus Level of Evidence of IV seems more appropriate, with an Inconclusive Grade.

We agree and this has been edited. The recommendation now reads:

_We cannot recommend for or against advising patients in regard to the following factors related to rotator cuff surgery:_

- Diabetes
- Co-morbidities
- Smoking
- Prior Shoulder Infection
- Cervical Disease

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<td>Cervical Disease</td>
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8A. This is not a very good guideline. They chose to look at factors affecting rotator cuff surgery. This is very vague. It includes not only rotator cuff tears but also rotator cuff tendinitis, impingement syndrome, etc. For the first two recommendations, I think these apply primarily if not exclusively to actual rotator cuff tears. If this is the case, this turns out to be a homogeneous group after all. However, for the last recommendation, their evidence pertains to a variety of rotator cuff conditions, and thus the recommendation is muddled.

We believe we addressed your concerns in the rewrite. The rationale for Recommendation 8A was clarified and the strength of recommendation for the confounding factors is illustrated in a table format as indicated above.
8A (effect of age) – Appears from their discussion that in their opinion, evidence for age affecting outcome is stronger than the contrary argument that age has no effect. However, objectively looking at the evidence, there is a lot of level 4 evidence for both declarations. Thus the evidence would seem to imply that this grade is inconclusive at this time (although this does not appear to be the opinion of the group) rather than Grade C.

We addressed your concerns in the rewrite. The rationale for Recommendation 8A (Now 7A) was clarified; the strength of the recommendation is weak. The work group evaluated the evidence and as stated at line 2227 in the guideline:

“Out of all 23 studies included, one author reported a negative correlation between increasing age and a patient-reported outcome measure.82 This study reported on 80 patients at 2 years after rotator cuff repair and concluded that older age was associated with worse DASH scores. The authors did perform a multivariate analysis confirming the relationship; therefore, this should be recognized as a significant finding. One other author79 reported VAS pain and reported age ranges for comparison groups. The findings are statistically significant but the authors do not define the size or direction of the effect.”

8A (effect of workers comp) – This recommendation is based on evidence from a heterogeneous collection of conditions, which speaks to problem of the way the guideline was constructed (see above). If you ignore this and just let this apply to any type of shoulder surgery, there is probably Level III evidence to support their guideline. As before, the evidence is not multiple levels. If the level II evidence is solid, this would be a level II recommendation, regardless of the volume of additional lower levels of evidence. In this case, I would consider this overall as level III evidence.

The strength of this recommendation (7A) is “moderate” based on Level II and III studies. The corresponding language of the guideline is “we suggest”. The rationale for this recommendation has been edited and now reads as follows:

“Several authors96-98 have evaluated the effect of Workers’ compensation on surgical treatment for rotator cuff disease including acromioplasty for tendonitis and repair of full thickness tears. Based upon one Level II study96 and two Level III studies,97, 98 the work group has determined that it is an option for physicians to advise their patients that workers’ compensation status correlates with less favorable outcomes after rotator cuff repair.

One study97 prospectively evaluated 107 shoulders (23 of which were receiving workers’ compensation) at an average of 45 months postoperative from an open rotator cuff repair with the UCLA score. Both groups were comparable with regards to patient age, sex, tear size, preoperative strength and active motion. At final follow-up, patients receiving workers’ compensation had significantly worse UCLA scores compared to those not receiving workers’ compensation. Another study98 prospectively evaluated 106 patients (40 of which were receiving workers’ compensation) at an average of 32 months after arthroscopic acromioplasty for rotator cuff tendonitis with the ASES score, the Simple Shoulder Test and a VAS pain scale. The authors report no statistically significant differences between groups with regards to each of these outcomes although the AAOS work group re-calculated the statistics and found workers’ compensation patients had significantly worse SST and VAS pain scores than those not receiving a claim. The last study98 prospectively evaluated 24 patients (12 receiving workers’ compensation) at an average of 3 years postoperative from an open acromioplasty for rotator cuff tendonitis.
with UCLA scores. At final evaluation, workers’ compensation patients had significantly worse improvements in pain compared to those not receiving Workers’ compensation. Based upon the above data, shoulder function as evaluated by the UCLA score, the Simple Shoulder Test and VAS pain scores were all inferior in workers’ compensation patients treated surgically for acromioplasty for rotator cuff tendonitis or rotator repairs compared to a non-workers’ compensation group.

This data supports the option of advising patients that workers’ compensation status correlates with less favorable outcomes after rotator cuff surgery.

10 - The evidence is not multiple levels. If the level IV evidence is reasonable, this should be a level IV recommendation, and in this case IV seems appropriate. IV, C.

For this recommendation we agree, the Level of Evidence for all four supporting studies was Level IV. This edit was made in the rewrite of the guideline.

11C - As before, the evidence is not multiple levels. If the level II evidence is solid, this would be a level II recommendation (actually it would not be; per the rules we specified a priori to the literature search, one level II study is defined in Table 4 as poor quality evidence), regardless of the volume of additional lower levels of evidence. In this case, I would consider this overall as level III evidence.

We agree that the overall level of evidence for this recommendation is Level III. This edit is made.

There is no place for their last sentence – “Our expert opinion is that arthroscopic repair techniques may result in less frequent deltoid-related complications when compared to open or mini-open repair techniques.” There is evidence for this recommendation, and that evidence apparently does not substantiate their opinion. This evidence based review is littered with opinions, but most are presented in absence of evidence. In the presence of evidence, this is particularly inappropriate.

We addressed this concern in the rewrite of the guideline and this sentence was removed from the rationale.

12A – These are very small studies. The Iannotti study is designed as a level II study, but with the small numbers, make sure this is powered well enough to provide strong level II evidence. Otherwise, this recommendation would be Level III evidence, Grade B.

The Level of Evidence for this recommendation is based on one Level II study and one Level III study. The strength of the recommendation is “moderate”. Line 3215 has been edited to reflect this edit. This does not change the overall strength of the recommendation.

15 – There is one study, and although it was conducted in level II fashion, since it compared an intervention to another intervention without a control group of some non infusion method of pain control, in terms of answering this guideline or question, this becomes level IV evidence. Thus I would suggest Level IV, Grade I.

Again, the Level of Evidence refers to the quality of the single study. When evaluating the body of evidence, the work group gave this recommendation an overall strength of “insufficient” because this single study was not generalizable and therefore, did not provide sufficient evidence to base the recommendation on.
We believe the rewrite of the guideline addressed your concerns.

Lines 530 – 540 – Establishing inclusion criteria.

“We developed *a priori* article selection criteria for our review. Specifically, to be included in our systematic reviews an article had to be a report of a study that:

- Evaluates a treatment for rotator cuff problems including:
  - rotator cuff tear or
  - rotator cuff related symptoms
    - Impingement syndrome (Subacromial impingement syndrome)
    - Rotator cuff disease
    - Rotator cuff tendonitis
    - Shoulder tendonitis
    - Subacromial bursitis
    - Subacromial tendonitis
    - Supraspinatus tendonopathy (tendonitis)

This is a big problem. These inclusion criteria are a big spectrum of disease, and some are hard to diagnose by strict objective criteria. If you’re looking at vague problems, you’re going to get vague and inconsistent answers, and it will be very difficult to interpret them, both within each study as well as comparing studies.

We hope the rewrite of the guideline addressed your concerns and clarified the areas you considered vague and inconsistent.

Line: 746.

“The values we used for MCIIs are derived from the published studies that enrolled only patients with rotator cuff tears (Table 2).” They developed MCIIs for based on a group with rotator cuff tears. If all they had looked at was rotator cuff tears which could have been an excellent guideline by itself, this would be fine. But they didn’t; they looked at all rotator cuff “problems” and thus criteria for MCII may not be consistent across all studies.

You are correct. Your criticism applies to Recommendation 4 “rotator cuff related symptoms” as the remainder of the guideline pertains to rotator cuff tears. Concerning Recommendation 4, there were two outcomes that have a known MCII (Alvarez et al., ASES and DASH). The reviewer is correct that the MCII used was from a patient population of rotator cuff tears. There is no known MCII for patients with “rotator cuff disease” for either of these scales. The MCII was included because rotator cuff disease can be a precursor to chronic rotator cuff tears. If the MCII was to be removed from these two outcomes the data would be identified as “not statistically significant” rather than “not sufficiently powered to detect the MCII; neither statistically or clinically significant.”

We have edited the text and figures to clearly identify the MCII is based on a patient population with rotator cuff tears.
As a general comment, this guideline was flavored with a lot of opinion; more than I am used to seeing. I would reiterate that I think it devalued the manuscript significantly to include a mixed bag of diagnoses. This would have been much more consistent and powerful if they would have stuck to something concretely definable, like rotator cuff tears alone. They also had difficulty assigning grades a times. They did not always understand that just because a study is designed at an initial certain level, it doesn’t always mean, and in fact rarely means, that this study provides that level of evidence. Studies often suffer from methodological problems, and require appropriate downgrading. This was not consistent, so raises concern about consistency of the recommendations throughout. They appeared to do a good job of exhaustively reviewing the literature, but they seemed to lack discipline in strictly complying with the usual rules that guide evidence based reviews.

We have edited the document based on the peer review comments received. We hope the rewrite of the guideline addressed your concerns, improved consistency in assigning grades of recommendations and better explains the downgrading of the level of evidence for studies in the document.

Dear Dr. Reitman,

We appreciate your thorough and honest review of these documents. We believe your input strengthened this document and improved the product we will ultimately present to the Board of Directors. Thank you.
American Academy of Orthopaedic Surgeons
[Optimizing the Treatment of Rotator Cuff Problems]
Guidelines Peer Review Form

ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:
- Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:
Name of Reviewer: James L. Carey
Address: 137 Carphilly Circle
City: Franklin State: TN Zip Code: 37069
Phone: (615) 875-0400 Fax: (615) 591-6336 E-mail: james.carey@vanderbilt.edu
Specialty Area/Discipline: Sports Medicine
Work setting: Academic
Credentials: M.D., M.P.H.

May we list you as a Peer Reviewer in the final Guidelines (GL)?
☐ Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society?
☐ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline?
☐ Yes ☐ No

Society Name: ___________________________________________
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.
If the boxes below are not checked and/or the reviewer does not attach his/her conflicts of interest, the reviewer’s comments will not be addressed by the AAOS nor will the reviewer’s name or society be listed as a reviewer of this GL. If a committee reviews the guideline, only the chairperson/or lead of the review must declare their relevant COI.

☐ I have declared my conflicts of interest on page 2 of this form.
☐ I have declared my conflicts of interest in the AAOS database; my customer # is __________
☐ I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.
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Reviewer Instructions
Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments in WORD format by end of day June 30, 2010.

Please indicate your level of agreement with each of the following statements by placing an “X” in the appropriate box.

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<td>15. The grades assigned to each recommendation are appropriate</td>
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Dear Dr. Carey,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline.

COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report.

I appreciate the rigorous process that resulted in the formulation of this draft.

Thank you.

The recommendations are appropriately supported by evidence, in general.

Thank You.

However, with respect to Recommendation 2, this reviewer notes an inconsistency with the following:

a) (line 959) Title: Full thickness tears in symptomatic patients

b) (line 961) Recommendation: Rotator cuff repair is an option for patients with chronic, symptomatic full thickness tears.

c) (line 967) Rationale: “Sixty patients without surgery were compared to seventy-seven with rotator cuff repair.” There is no mention of whether these tears were acute or chronic.

If this study does not specifically address chronic tears, then I suggest that the authors consider removing “chronic” from this recommendation.

Alternatively, if this study does specifically address chronic tears, then I suggest that the authors consider adding “chronic” to the title and documenting in the rationale that this study specifically addresses chronic tears. This clarification should help define distinction from Recommendation 5.

Based on your comments, additional text has been added to the rationale of Recommendation 2 clarifying the patient population at Line 968. The study you question is by Tabata (1987). We have attached this study for your review. Patients within each group of this study were identified as follows:

“In group A, tears were non-traumatic in 73% of cases and traumatic in 27% of cases. In group B, tears were non-traumatic in 32% of cases and traumatic in 68% of cases.”

The work group defined Group A as containing a majority of patients with chronic symptoms.

For reference:
Recommendation 2 states the following:
“Rotator cuff repair is an option for patients with chronic, symptomatic full thickness tears.”
Grade of Recommendation is weak

Recommendation 5 states the following:
“Early surgical repair after acute injury is an option for patients with a rotator cuff tear.”
Grade of Recommendation is weak

Dear Dr. Carey,

We sincerely appreciate the time, effort and expertise you have contributed to this review process. We believe your comments help strengthen the document we ultimately present to the AAOS BOD for approval. Please accept our sincerest Thank-you for your input.
OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

☑ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure
American Academy of Orthopaedic Surgeons
[Optimizing the Treatment of Rotator Cuff Problems]
Guidelines Peer Review Form

ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:
  • Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
  • Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:
Robert C. Manske
Wichita State University Department of Physical Therapy
1845 North Fairmount
Wichita, KS 67260-0210
Phone 316-978-3604
E-mail: Robert.manske@wichita.edu

Specialty Area/Discipline: Physical Therapy
Work setting: University and Outpatient Physical Therapy Center
Credentials: PT, DPT, MEd, SCS, ATC, CSCS

May we list you as a Peer Reviewer in the final Guidelines (GL)?
X Yes ☐ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society?
XYes ☐ No

If yes, may we list your society as a reviewer of this guideline?
XYes ☐ No

Society Name: American Society of Shoulder and Elbow Therapists
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.
If the boxes below are not checked and/or the reviewer does not attach his/her conflicts of interest, the reviewer’s comments will not be addressed by the AAOS nor will the reviewer’s name or society be listed as a reviewer of this GL. If a committee reviews the guideline, only the chairperson/lead of the review must declare their relevant COI.

☐ I have declared my conflicts of interest on page 2 of this form.

☐ I have declared my conflicts of interest in the AAOS database; my customer # is __________

X I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.
Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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<td>Within the past twelve months, have you or a member of your immediate family served on the speakers bureau or have you been paid an honorarium to present by any pharmaceutical, biomaterial or orthopaedic product or device company?</td>
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<td>If YES, please identify: Vice President of the Sports Physical Therapy Section of the APTA</td>
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**Reviewer Instructions**

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments in WORD format by end of day **June 30, 2010**.

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**Please indicate your level of agreement with each of the following statements by placing an “X” in the appropriate box.**

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Dear Dr. Manske,

We sincerely appreciate the time and expertise you have given the Academy. Your review of both the original document and the edited document have improved the final guideline we will present to the Board of Directors. Please find below a point by point response to your concerns and your original comments for reference.

COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report.

As one of the three reviewers from the American Society of Shoulder and Elbow Therapists I would like to thank the American Academy of Orthopaedic Surgeons and the Guidelines Committees for inviting myself, Reg, and John to participate in the peer review of Optimizing the Management of Rotator Cuff Problems. We appreciate the great length you went to in finding evidence that supports surgical and non surgical approaches to treatment of rotator cuff injuries. I feel that the current version of the guidelines appropriately addressed the majority of the recommendations that we provided during our initial review in January of 2009.

Thank you.

I have to concur with Reg Wilcox in an area that has not been adequately addressed which is the area of intended users. On line 565 the users only list orthopedic surgeons and qualified physicians managing patients with rotator cuff problems. If this is simply because this is published by the AAOS and distributed by their members then so be it. I agree that this list is incomplete as many others in the healthcare team should also include: physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians and physician assistants.

Based on your comments, as well as others, the following text was added to the guideline at line 570:

“Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians, physician assistants and other healthcare professionals who routinely see this type of patient in various practice settings may also find this guideline useful.”

Additionally on page 26-33 – Recommendation 3A - several studies that we recommended were not included that demonstrate positive outcomes following conservative or non operative management of rotator cuff tears. Also on pages 45-65 – Recommendation 4A – there is no mention of several articles that describe randomized controlled trials for shoulder impingement using exercise that were not included in the final addition.

Please see the responses to your original comments listed below. We reviewed all of the studies you suggested for inclusion. We have listed the reason for exclusion or disposition of the studies for your convenience.

We applaud your efforts that support use of exercise and manual therapy in Recommendation 4a. There appears to be fairly strong (moderate) evidence to support use of manual therapy in conjunction with exercise for conservative treatment of rotator cuff tears.

There is moderate evidence to support Recommendation 4A. One should consider the body of evidence for the recommendation and not the level of evidence for a single study.
OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

X  Strongly recommend
☐  Recommend (with provisions or alterations)
☐  Would not recommend
☐  Unsure

I would recommend these guidelines be accepted for finalization & publication. I commend the American Academy of Orthopaedic Surgeons and the Guidelines Committees for their extensive review and recommendations presented in this guideline.

It is certainly an honor to have been chosen to contribute to this guideline and I look forward to continued collaboration between the AAOS and the American Society of Shoulder and Elbow Therapists.

Original Comments

On behalf of the American Society of Shoulder and Elbow Therapists we would like to thank the American Academy of Orthopaedic Surgeons and the Guidelines Committees for inviting us to participate in the peer review of Optimizing the Management of Rotator Cuff Problems. We applaud your efforts to find evidence that supports surgical and non surgical approaches to treatment of rotator cuff injuries. We hope our constructive comments will help you further refine the evidence based recommendations as well as the rational presented.

Dear Drs. Wilcox, Manske and Basti,
Thank you for all the work you have put into reviewing this guideline. We appreciate all of your thoughtful input. In order to address your comments and edits, please find below a point by point response that has been reviewed and approved by the chair and vice-chair of this guideline. Changes to the draft were made as a result of your thoughtful input and these changes improved the final document prior to sending the draft to the approval process.

Introduction:

Page 3, line 457. We feel this statement should be referenced.
Referenced statements have been placed in the rewrite of the document.

Page 3, line 458. We feel this statement should be referenced.
Referenced statements have been placed in the rewrite of the document.

Page 3, line 476. Emotional and Physical Impact of Osteoarthritis of the Knee – Is this a correct title? This typographical error has been edited and corrected in the rewrite of the document.
Are the comments related to “Surrogate” necessary since surrogate outcome measures are not included?

Our opinion, as well as that of others who produce evidence-based products, is that this information may be helpful. Readers of guidelines are of varying degree of sophistication and sometimes the definitions and explanations are helpful for them.

**Statement #1: The recommendations are clearly stated**

We agree that the recommendations are clearly stated, however we feel that certain words need an operational definition and clarification such as Physical Therapy (line 1745), exercise (922), activity modification (lines 1143, 1154, 1164).

See response to statement # 8 for further clarification.

We would define these terms based on the supporting evidence. We had no studies that referenced exercise or activity modification (Lines 922, 1143, 1154, and 1164). For physical therapy, Line 1745, the studies defined physical therapy as a form of “supervised” therapy, however the details of each program can be found in the referenced studies. In the most recent draft, we changed to recommendation to “exercise” and considered any study that evaluated an exercise program whether supervised or home based.

**Statement #2: There is an explicit link between the recommendations and the supporting evidence**

After a thorough review of this document we agree with most all of the evidence and rationales for each of the recommendations. However, after reading the summary of recommendations (lines 25 thru 297) without the evidence and rational accompanying the statements, it is felt that one can develop a sense of negativity when reading the recommendations alone. Due to the subject matter and format, the document is quite large and may impede one’s ability to fully digest its full critique of the best available literature presented. We are concerned that this could possibly lead to confusion, misinterpretation, and misuse.

We add a disclaimer to encourage all readers to consult the rationales stating:

This summary does not contain rationales that explain how and why these recommendations were developed nor does it contain the evidence supporting these recommendations. All readers of this summary are strongly urged to consult the full guideline and evidence report for this information. We are confident that those who read the full guideline and evidence report will see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility. This summary of recommendations is not intended to stand alone. Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient and physician.

We realize that identical formats have been established by the AAOS and are wondering if you have received feedback concerning this after their publication.

Yes, peer reviewers first asked for a list of summary statements and then asked that the disclaimer be made prominent by placing prior to listing the summary.

Additional concern is that readers will make an abbreviated read and bypass the rationales. Although you do state that you strongly urge the readers to consult the full guideline, our suggestion is to set the statement in a different font and/or in bold. This will help to highlight the importance of consulting the full document before it is used as a tool to aid the clinician in clinical decision-making and treatment.

We have bolded the disclaimer for clarification.
Statement #3: *Given the nature of the topic and the data, all clinically important outcomes are considered:*

3B - Although we understand the concern for lack of evidence regarding several treatment modalities such as iontophoresis, phonophoresis, massage, ice, and heat, we think it is reasonable that none of those modalities would, nor should be administered in isolation either during treatment or in a clinical trial. Hence, there will likely never be strong randomized trials to support or refute their use. We, in fact, believe that it may even border being unethical in putting a patient into a research protocol to test in isolation any of these modalities. It is our experience that in all instances, these forms of modalities are done in conjunction with other forms of rehabilitation. Furthermore, we would not necessarily assume that any of these modalities in isolation will substantially have a positive or negative effect on those patients with rotator cuff tears. Clinically it appears to be a useful modality in a total treatment plan to reduce pain, improve function, and the quality of ADL. It is evident that further research is needed.

We agree and hope this guideline will spur additional high quality research to answer the questions formulated for this guideline that have no supporting evidence, including defining appropriate nonoperative protocols that may include the modalities listed.

4F – There appears to be additional studies that indicate a positive effect of physical therapy treatment in the absence of a full thickness rotator cuff tear (impingement). We applaud your inclusion of both Bang and Walther, and would like to present the following study:


This demonstrated decreases in pain and function in both groups – self training after instruction, or by the addition of soft tissue and joint mobilization techniques. Although both groups improved, the groups that received mobilization had significantly more improvement than the self directed exercise group. These findings support that of Bang et al.

Senbursa et al. (2007) was identified by our search, reviewed and excluded from recommendation 4F. Although impingement syndrome was included in this recommendation, the workgroup agreed that outlet impingement syndrome was not equivalent to impingement syndrome and studies treating this patient population should be excluded.

Statement #4 *The guidelines target audience is clearly described*

In reference to line 413 -428

We agree that the target audience is clearly defined however we feel it is incomplete. We note that the list of intended users of this guideline is not a comprehensive list of healthcare providers that evaluate, assess, and advise patients with rotator cuff dysfunction. The intended users span from orthopaedic surgeons and all qualified physicians, and skips to insurance payers, governmental bodies and health policy decision-makers. Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians and physician assistants routinely see this type of patient in various practice settings. In addition, it is not clear who a “qualified physician” describes. Would the authors of this guideline feel that a primary care physician, primary care sports medicine physician, rheumatologist, and physiatrist be considered a qualified physician? If so, it may be clearer to the reader to list out these disciplines clearly.
Additional text has been added at line 570:
“Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians, physician assistants and other healthcare professionals who routinely see this type of patient in various practice settings may also find this guideline useful.”

Following the review of this guideline, it is apparent that it is not intended to be a guideline for the work-up/evaluation/assessment of rotator cuff dysfunction but rather a guideline reviewing and recommending treatment options based on the best available evidence. We would recommend a statement in the introduction of this document to this effect. This would make it clearer to the reader. We trust that anyone that the authors feels falls into the ‘qualified healthcare provider’ has the basic skill set to appropriately evaluate and diagnosis rotator cuff dysfunction.

We believe we have clearly stated the intent of the guideline in the “Goals and Rationale” section:
Line 394: The purpose of this clinical practice guideline is to help improve treatment based on the current best evidence.

Line 406: We created this guideline as an educational tool to guide qualified physicians through a series of treatment decisions in an effort to improve the quality and efficiency of care.

**Statement # 5 The patients to whom this guide is meant to apply are specifically described**

We agree with most of the search criteria as outlined in this guideline. It appears thorough and comprehensive for the topic at hand. However, by not including studies that looked at partial thickness tears certainly both limits the evidence that is available as well as the generalizability of this guideline to many patients seeking guidance for rotator cuff dysfunction.

We agree that the majority of the guideline is focused on patients with full-thickness tears. The Academy is constrained by time and budget requirements and must limit the focus/scope of all guidelines developed so that they remain within these constraints.

We agree that the exclusion of studies that had enrolled subjects that also had an arthroplasty, concomitant capsular release, inflammatory arthropathy, coexisting fractures, and wheelchair/weight bearing shoulder related issues is appropriate. However, this guideline does not mention either excluding or including content or studies with subjects with other concomitant pathology such as biceps dysfunction, labral tears, as well as SLAP tears. As the authors know, many patients with shoulder pathology do not have a rotator cuff tear in isolation; hence, by not discussing recommendations for patients with the above concomitant pathology, it may significantly limit the usefulness of this guideline in clinical practice.

Based on your comments, we reviewed the 74 included studies in this guideline. Concomitant pathology such as biceps dysfunction, labral tears, as well as SLAP tears would not have been reason for exclusion; however, the majority of authors do not discuss these pathologies in their papers either as existing in the included patient population or as reason for exclusion. We are limited by the information reported by the authors of the included studies. The work group agrees that it is unlikely that there are any “absolutely clear cuff-only studies because the condition is commonly found with co-variables.”

**Statement # 6 The criteria used to select articles for inclusion are appropriate**
We agree. However, even though these studies were excluded from review due to the inclusion criteria used, they nonetheless influenced the rationale.

We have edited the final document to limit the inclusion of information not in the included studies. For the introductory sections of the guideline, the included studies do not address the issue of incidence, prevalence, risk factors, etc. We specifically search out additional studies that answer these informational areas. The rewritten rationales should not reference these studies however. The rationales for each recommendation include only information from the supporting evidence (the included studies).

Perhaps with these types of studies – i.e., studies with high level, narrowly defined inclusion criteria - maybe the inclusion criteria is too narrow and is not reporting the true picture of what is effective and is clinically recognized as effective treatment. This is perhaps an example of the inherent limitations of such strict inclusion criteria. We appreciate that the work group is eager to define best practice based on the best available evidence for clinical care, and identify gaps in science so that in the future we’ll have inclusive and higher quality research.

We agree that better high quality research is needed in the management of rotator cuff disease.

**Statement # 7 The reasons why some studies were excluded are clearly described**
We agree that is was very clear and well defined.

**Statement # 8 All important studies that met the inclusion criteria are included:**
Recommendation 3A
Reference: lines 921-951

We feel the level of evidence for an exercise program for non-operative treatment for patients with a rotator cuff tear can further be supported with the following additional studies. We are not sure of anyone who would not attempt conservative treatment prior to surgery in the appropriate patient population. Several studies that show positive outcomes following physical therapy interventions include multiple case series such as:


  This study was not identified by our search strategy. It was not available during our final database search on October 2008. Although this article was published in the October issue there is an unfortunate lag with databases between date of publication, date of availability and date of indexing. This is beyond AAOS control and is related to the time taken for a publisher to provide PubMed information and the time needed for PubMed to make the information available to the public. If this article meets all inclusion criteria it will be added to any future guideline updates.


  Study identified, reviewed and excluded. Exclusion reason – less than 80% follow-up (see page 17 of Evidence Tables)

Study identified, reviewed and excluded. Exclusion reason – less than 80% follow-up (see pages 2, 5, & 8 of Evidence Tables)


Study identified, reviewed and excluded. Exclusion reason – less than 80% follow-up (see pages 8 & 17 of Evidence Tables)

Recommendation 4A
Reference lines 1175-1177
Several studies existing that support the positive benefit of therapeutic exercise when compared to surgery for sub-acromial impingement are:


Study identified, reviewed and excluded. Exclusion reason – A validated scale was not used by the authors (see page 36 of Evidence Tables).


This article was identified by our search, recalled and excluded. The comparison made in Haahr et al. (2005) is surgery vs. exercise. This study was not applicable to any of the recommendations asked.

Recommendation 4B
Reference lines 1204 -1225
This guideline briefly raises the point of manual therapy as an intervention for patients with rotator cuff dysfunction, by including the Bang & Deyle article, in recommendation 4B; however, the premise of this recommendation is exercise and not manual therapy. We feel that the authors of this guideline have misstated the conclusion of this article to support recommendation 4B.

We do not believe we have misstated the conclusion of this article to support Recommendation 4B. We do not report the author’s conclusions and as a matter of fact only read the methods and results sections of included studies. Our conclusions are based on the statistics reported in the study for the original hypothesis, not the discussion section of a given article or an author’s conclusions. In this trial, subjects in both groups (exercise and exercise plus manual therapy) significantly improved their “functional assessment questionnaire scores” and significantly reduced their VAS scores for pain after treatment. (see page 133 of the study).

However, the results reported between groups were “post hoc pairwise comparisons” (or a subgroup analyses after the data was collected). Based on this post hoc analyses, the author concludes that subjects with shoulder impingement syndrome who received manual therapy in addition to supervised exercise, did better in terms of strength gains, pain reduction, and functional gains than those who were given supervised exercise.

Our recommendation states:
We suggest that patients who have rotator cuff-related symptoms in the absence of a full thickness tear be treated with an exercise program.

The treatment comparison for this study is indicated in Table 29, page 46, and correctly indicates the comparison is “exercise with manual PT vs. exercise”. The summary table also correctly illustrates that at the final visit the results favored exercise with manual PT. For clarification and to avoid misunderstanding by other readers, we have added the following text to the rationale (bolded):

“One study reported on 24 patients undergoing an exercise program and noted significantly improved pain scores on the VAS [visual analog scale] after 8 weeks of treatment; post hoc pairwise comparisons of the two groups in this study showed significantly more improvement in the exercise plus manual therapy group using a composite pain measure.”

As stated in our disclaimer, we believe specific treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient and physician. Since the studies to support this recommendation present different exercise protocols, it is ultimately up to the individual patient and their physician to determine the best treatment plan applicable.

In addition, a few other articles exist that demonstrate better outcomes for patients, with shoulder impingement syndrome, receiving manual therapy in addition to exercise. They include:


  This article is identified, reviewed and excluded. Exclusion reason - Outlet impingement syndrome patients.


  This article is identified, reviewed and excluded. Exclusion reason - Less than 10 patients in any treatment group (see page 36 of Evidence Tables).


  This article was published after our last database search (October 6, 2008).

Based on the above evidence, we would recommend a separate guideline recommendation specific to the use of manual therapy in addition to exercise for patients with rotator dysfunction in the absence of a full thickness tear. This stems from the definition of manual therapy being “the application of an accurately determined and specifically directed manual force to the body, in order to improve mobility in areas that are restricted; in joints, in connective tissues or in skeletal muscles.”
Based on the Academy’s available time and budget constraints, new recommendations cannot be added following the literature search for the guideline. Again, we believe the exact physical therapy treatment or exercise protocol applicable to the individual patient relies on mutual communication between patient and physician as well as other healthcare professionals treating the patient.

Recommendation 4F
Reference lines 1743 - 1783
There appear to be multiple studies that indicate a positive effect of physical therapy treatment in the absence of a full thickness rotator cuff tear (impingement). The study by Senbursa et al. demonstrated decreases in pain and function in both groups – self training after instruction or by the addition of soft tissue and joint mobilization techniques. Although both groups improved, the groups that received mobilization had significantly more improvement than the self directed exercise group.

These findings support that of Bang et al. This study is included.


This article is identified, reviewed and excluded. Exclusion reason - Outlet impingement syndrome patients.

We agree that the evidence that is available supporting the efficacy of physical therapy for patients with rotator cuff dysfunction may be inconclusive due to a dearth of high quality randomized controlled trials available for review. One major issue is that many studies do not adequately define what physical therapy interventions were, or are, included in their clinical trials. Hence, strong conclusions and the generalizability of many studies are lacking. Physical therapy can include a multitude of treatment interventions including: manual therapy, exercise, multiple local modalities, muscle reeducation, patient education, and proprioception training.

We agree that physical therapy and or exercise protocols are not well defined; we were bound by the definitions provided by the authors of the studies. From the studies found, the work group was broad and inclusive. We hope the guideline will spur better quality research that will help identify specific treatment protocols and interventions that will improve the care of patients with rotator cuff disease.

Thus, we recommend that both future studies and this guideline better define the interventions that constitute their operational definition of physical therapy. The term rehabilitation may be a better descriptor. In this day and age, physical therapists are not solely the ones rehabilitating patients with rotator cuff dysfunction. If we, as physical therapists, can do a better job describing and evaluating what rehabilitation protocols and interventions we are using, we will hopefully have better evidence to support, or alter, the recommendations outlined in this document in a future version.

One area that we, as physical therapists, can do a better job at in our clinical research, is specifically describing the exercise interventions that are most optimal for a given patient presentation and outcome. One specific example of an area for better description is exercise, not only the type of exercise but the frequency, duration, and specific selection of which exercises are best for a given patient presentation/diagnosis/impairment. There are many operational definitions of exercise when it comes to the shoulder. These include but are not limited to:

- Rotator cuff strengthening exercises (isometric, isotonic, isokinetic, etc…)
• Rotator cuff / joint capsule stretching exercises
• Periscapular strengthening exercises to enhance endurance, power, or better positioning of the scapula to enhance the biomechanics of the glenohumeral joint.
• General upper quarter strengthening exercises
• PROM / AAROM / AROM

Lumping evidence regarding exercise into one bucket will likely always produce inconclusive and soft evidence for its effectiveness. Certainly this is an area for physical therapists and other rehabilitation professionals to improve upon in our clinical research.

We agree and the chair of the guideline will consider your comments as he writes the “Future Research” section of this guideline.

Statement # 10 The methods are described in such a way as to be reproducible
Thank you.

Statement # 11 The statistical methods are appropriate to the material and objectives of this guideline
Thank you.

Statement #12 Important parameters addressing the study result are systematically addressed
Thank you.

Statement # 13 Health benefits, side effects, and risks are adequately addressed
Lines 1982-90, the authors speak of high risk/low risk but do not define a base level. High risk / low risk in reference to what level of risk?

We have removed these expert opinion statements from the rationales in the edited document.

Lines 1155-1159, 1986-1988, 939 refer to the “cost burden” of various rehabilitation approaches, but never mentions cost with respect to conservative vs. operative treatment of rotator cuff problems. There were also no cost analysis or references cited. Perhaps the discussion of cost is not appropriate for this type of guideline. If cost is going to be mentioned, it should be considered throughout the guideline with evidence based cost analysis for all treatment mentioned in this document.

We agree. Cost and risk analyses are beyond the scope of this guideline; references to this have been deleted in the edited document, specifically at lines 3353 and 3364.

Statement # 14 The writing style is appropriate for health care professionals and Patients
It seems inconsistent that the same guideline would simultaneously be aimed at both physicians - who as defined by the criteria, have a high level of training, clinical experience, and expertise in the subject matter – and patients who’s level of knowledge can be variable and/or nonexistent. Also the format of this text does not lend itself to easy interpretation by non-clinical personnel.

We agree. The guideline is written for the healthcare professional and methodologists who wish to perform an intellectual audit of the guideline. We hope that we can prepare versions suitable for patients in the near future.

Statement # 15 The grades assigned to each recommendation are appropriate
We agree that the grades are appropriate given the amount of studies ultimately selected for the review, considering the narrow inclusion criteria.

The inclusion criteria are standard criteria accepted by the evidence based medicine community.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (Check One)

Strongly recommend

Recommend (with provisions or alterations) ___X___

Would not recommend

Unsure

COMMENTS:
Please provide the reason(s) for your recommendation.

We would recommend these guidelines be accepted for use in clinical practice with consideration of our critique. Our critique as outlined above offers some suggestions to enhance the usefulness of this guideline. Additional literature has been provided to support the recommendations and clinical opinions of the authors where evidence is not as strong. It is our hope that this additional information may give perspective to better define some clinical definitions.

We agree. We also believe that this is a better document as a direct result of the time our volunteers donate to the advancement of evidence based medicine.

We commend the American Academy of Orthopaedic Surgeons and the Guidelines Committees for their extensive review and recommendations presented in this guideline. We consider it an honor and a privilege to have contributed to this guideline through the peer review process. We welcome continued collaboration. Ultimately, this document and its continued development will enhance the management and the quality of care that we offer to our patients.

Thank you again for your time and expertise in reviewing this document. Your input has served to strengthen the evidence presentation and improve the final draft that will be sent for approval.
American Academy of Orthopaedic Surgeons  
[Optimizing the Treatment of Rotator Cuff Problems]  
Guidelines Peer Review Form

ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:
• Your review will be published on the AAOS website with our explanation of why we did nor did not change the draft document in response to your comments
• Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:
Name of Reviewer    Philip McClure ________________________________________
Address__Arcadia University__450 S Easton Rd_____________________________________________
City__Glenside______________________ State___PA______________ Zip Code__19038_________
Phone __215.572.2863_________________________Fax __215.572.2157_________________E-mail_mcclure@arcadia.edu_____
Specialty Area/Discipline: ___Physical Therapy____________________________________
Work setting: __University and Out pt PT_____________________Credentials: ___PT, PhD, FAPTA___________________

May we list you as a Peer Reviewer in the final Guidelines (GL)?       X☐ Yes ☐ No
PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society?       X☐ Yes ☐ No

If yes, may we list your society as a reviewer of this guideline?       X☐ Yes ☐ No

Society Name: __American Physical Therapy Assoc_________________________________________
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.
If the boxes below are not checked and/or the reviewer does not attach his/her conflicts of interest, the reviewer’s comments will not be addressed by the AAOS nor will the reviewer’s name or society be listed as a reviewer of this GL. If a committee reviews the guideline, only the chairperson/or lead of the review must declare their relevant COI.

☐ I have declared my conflicts of interest on page 2 of this form.
☐ I have declared my conflicts of interest in the AAOS database; my customer # is __________
☐ I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.
## REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

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<td>If YES, please identify: Journal of Orthopedic and Sports Physical Therapy, Journal of Hand Therapy</td>
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Review Instructions
Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments in WORD format by end of day June 30, 2010.

Please indicate your level of agreement with each of the following statements by placing an “X” in the appropriate box.

<table>
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<tr>
<th>Statement</th>
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<td>15. The grades assigned to each recommendation are appropriate</td>
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Dear Dr. McClure,
Thank you for all the work you have put into reviewing this guideline. We appreciate all of your thoughtful input and your willingness to review both the original document and the revised guideline. In order to address your edits, please find below a point by point response that has been reviewed and approved by the chair and vice-chair of this guideline. Changes to the draft were made as a result of your original input as well as your most recent comments. Your original comments and our responses are also listed below for your reference. You time, input and expertise have improved the final document we will ultimately submit to the approval process.

COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report.

Overall the report is clear and very complete, yet still very manageable to navigate and use. Very well done! Thank you.

Below represents some confusion on my part when trying to check references.
I am very confused as there appear to only be 42 included articles that are numbered as references in the “Included Articles” yet higher numbers than 42 are often cited as references. No doubt I am missing something basic in the structure of the report.

For example: from Recommendation 4a Rationale
Several Level II studies 23, 61, 62 report the beneficial effects of exercise in decreasing pain 1338 and improving function in patients with rotator cuff related symptoms without a full 1339 thickness tear.

From only a brief check, it appears that several references are missing from the Included / Excluded list but are cited in Evidence Table 26 (listed below). I wonder if there is a more systematic error in listing references?
Cheng, et al.2007
Rahme, et al. 1998
Taheriazam, et al.2005

This is an error in our reference manager program that creates and formats our bibliography. It is corrected.
There are seventy-four included articles for this guideline (please see the evidence tables for each recommendation); fifteen were used to answer multiple recommendations. There are one hundred seventeen references listed because we also identify for the reviewer the references used to support the informational portions of the guideline and the methods section. Based on you comments, I have sent you an additional CD containing the edited document and corrected reference list. This information has also been added to the guideline at line 814.

Original Comments

This is an impressive body of work that was obviously very thorough and generally very well written and easy to follow. I reviewed the document with a focus on the rehabilitation aspects of rotator cuff management.

Thank you for kind comments.
My major recommendation is AVOID the use of the term “physical therapy” to describe a treatment. (especially Recommendation 4F) “Physical Therapy” is a professional discipline and does not provide any meaningful description of treatment given. In virtually all studies quoted, the “physical therapy” consisted of a supervised exercise program of some sort, with or without manual therapy or a home exercise program (taught by a physical therapist). These should be distinguished from other treatments sometimes applied by physical therapists such as the various thermal and electrical modalities, which are appropriately separated in the recommendations.

We believe we addressed this comment in the edited document. Please be aware however, that we use the evidence to define terms. In other words, we defer to the definitions the author’s use in their original work.

I would strongly recommend that terms such as “exercise”, “strengthening”, “stretching”, or “resistive exercise” be used to describe the interventions in place of “physical therapy” where appropriate as they often are used in the text. In a few places there is a comparison between supervised and home exercise programs in which case it is appropriate to describe who “supervised” as well as who taught the home exercise program.

Rather than listing all the instances where “physical therapy” is used inappropriately, I would strongly recommend “searching” the term “physical therapy” in the document and replacing with an appropriately descriptive term such as those listed above.

Please see the comment above.

The somewhat baffling thing the imprecise terminology produced is that recommendation 4b reaches a “B” level grade of recommendation for “exercise” using almost the same group of studies cited in recommendation 4f for “physical therapy” where an “inconclusive” recommendation is made despite the fact that all of the “physical therapy” studies cited utilized an exercise approach. Also unclear is why “physical therapy” was grouped with PEMF (an acronym that needs to be defined earlier) in recommendation 4f.

We believe we have addressed this concern in the edited document.

PEMF is now defined in the summary of recommendations in the beginning of the document.

Potential Additional studies not cited or reviewed

At least 1 key exercise study (RCT) is missing and not cited in the studies not included:


This study was identified by our search but not recalled. The patient population was limited to male construction workers who were regularly exposed to overhead work (one third of their day spent doing overhead work). We did not find this study applicable to the general patient population.

Another study that should be reviewed is


This article was identified by our search, recalled and excluded because it was not the “best available evidence.”
I also wondered why often cited studies by Brox et al ’93 and ’99 were not included.

These studies were identified by our search, reviewed and excluded because they did not use a validated scale.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

- Strongly recommend
- Recommend (with provisions or alterations) __X__
- Would not recommend
- Unsure

COMMENTS:
Please provide the reason(s) for your recommendation.

The imprecise use of the term “physical therapy” is very problematic and easily remedied.

We believe the edited document addresses this issue.
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- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:

Name of Reviewer: Walter Stanwood
Address: 95 Tremont Street, Suite 1
City: Duxbury
State: MA
Zip Code: 02332
Phone: 7819342400
Fax: 7819340001
E-mail: wjstanwood@yahoo.com

Specialty Area/Discipline: Shoulder/elbow and sports medicine
Credential: ABOS certification and sports medicine subspecialty certification

Work setting: Private practice

May we list you as a Peer Reviewer in the final Guidelines (GL)?

☐ Yes □ No

Are you reviewing this guideline as a representative of a professional society?

☐ Yes □ No

If yes, may we list your society as a reviewer of this guideline?

☐ Yes □ No

Society Name: ________________________________

(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

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<td>If YES, please identify: Board of directors, Massachusetts Orthopaedic Association</td>
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**Reviewer Instructions**

Please read and review this Draft Clinical Practice Guideline and its associated Technical Report with particular focus on your area of expertise. Your responses are confidential and will be used only to assess the validity, clarity and accuracy of the interpretation of the evidence. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report. If you need more space than is provided, please attach additional pages.

Please complete and return this form electronically in WORD format to wies@aaos.org; please contact Jan Wies at (847) 384-4311 if you have any questions. Thank you in advance for your time in completing this form and giving us your feedback. We value your input and greatly appreciate your efforts. Please send the completed form and comments in WORD format by end of day **June 30, 2010**.

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**Please indicate your level of agreement with each of the following statements by placing an “X” in the appropriate box.**

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<th>Statement</th>
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<td>15. The grades assigned to each recommendation are appropriate</td>
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Dear Dr. Stanwood,

We sincerely appreciate the time, effort and expertise you have contributed to this review process as a member of the Guidelines and Technology Oversight Committee. We believe your comments help strengthen the document we ultimately present to the AAOS Board of Directors for approval. Please accept our sincerest Thank-you for your input.

COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report.

Overall this is a very well designed and executed guideline. I have some suggestions below.

Thank you.

In the paragraph INTENDED USERS on line 565 it might make more sense to be more inclusive than exclusive in describing the intended users. Removing the word qualified would help. I think any internist would feel qualified, as well as family practice and pediatricians.

Based on your comments, as well as comments from others, we have removed “all qualified” from line 565 and added text at Line 570, in the Intended Users Section as shown below:

“Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians, physician assistants and other healthcare professionals who routinely see this type of patient in various practice settings may also find this guideline useful.”

In the presentation of the guidelines I would suggest placing recommendation number 4 as number 1 as this creates a more natural flow of treatment of rotator cuff symptoms to rotator cuff tears.

We do not reorder the recommendations to prevent bias. The work group is asked to consider the treatment pathway when they construct the preliminary recommendations. This work group began by considering asymptomatic patients (Recommendation 1), chronic, symptomatic patients (Recommendation 2), and then non-operative treatments (Recommendations 3a, 3b, 3c and 4).

Recommendation 10a (line 136) reads awkwardly. I know that the word “option” is listed as how it needs to be stated given the level of evidence, but it doesn’t make sense in the context of the statement. You always want tendon to bone healing. It appears that there might be room to expand the verbiage allowed at each level of evidence.

We carefully considered your comments but cannot change the language of the guideline at this time. The strength of the recommendation is directly tied to the language of the guideline (see Table 5, Line 845). The strength of the recommendation also indicates the confidence one can have that the recommendation will not be overturned by future research. For recommendation 10a, three level IV studies support the recommendation making it an “option”.

Recommendation 10a

It is an option for surgeons to attempt to achieve tendon to bone healing of the cuff in all patients undergoing rotator cuff repair.

Per the work group chair and vice-chair, patients have reported feeling improvement in pain when tendon to bone healing is not achieved and bone-tendon healing is not “always” needed as the literature clearly demonstrates that excellent clinical results can be obtained in the absence of healing. This is in part why the work group initially posed the preliminary recommendation.

As stated in the rationale (Line 2984), it is a primary biological goal of the surgery to achieve healing of the tendon to bone; this is a surrogate outcome for patient improvement in pain, strength and function. Surrogate outcomes are substitutes for patient-oriented outcomes that directly show whether a patient is living longer, healthier, and/or happier. Based on the weak evidence found to support this recommendation, additional research needs to be done.
American Academy of Orthopaedic Surgeons  
[Optimizing the Treatment of Rotator Cuff Problems]  
Guidelines Peer Review Form

In recommendation 13b (lines 3391-3395): It might help to further clarify that this includes all forms of range of motion exercises, i.e. passive, active, active assisted.

Based on the reviewer comments, this clarification was added. The rationale now reads as follows:

“After a systematic search, no clinical data was found supporting or refuting a negative or positive effect of range of motion exercises (passive, active or active assisted) for post-operative rehabilitation after repair of a full thickness rotator cuff tear on tendon healing or outcomes after rotator cuff repair. Therefore, the work group could not recommend for or against the timing of range of motion exercises in the post-operative period.”

In Evidence Table 3 it lists a study by Tabata et al. that is retrospective. I performed a search on the NCBI site and could not locate an article from 1987. I presume this is a typographical error and it is indeed a study that does exist and is prospective?

Our Medical Librarian searches numerous databases including but not limited to PubMed. This study may have come from CINAHL, EMBASE or the Cochrane Controlled Trials database (please see Appendix III, page 265). Further, these databases are maintained and reviewed periodically. Our Medical Librarian informs me that this study could also have been removed from one of these databases for any number of reasons. Regardless, we have forwarded this study to you for your review. Comparative retrospective studies are included; albeit that they represent evidence that is of lower quality than good controlled trials.

In Evidence Table 74 it lists a study by Youm et al. that is retrospective. Why is this study included? The fact that it is retrospective should disqualify it immediately. In addition, there is one level II and one level III study that are both prospective and are already included as the supporting evidence.

This study is a retrospective comparative study and is included because it compares mini-open repair to arthroscopic surgery. Retrospective studies are excluded. Retrospective comparative studies are included in this guideline if they represent the best available evidence. The other two included studies that you reference, Mohtadi (2008) and Ide (2005), study open repair to arthroscopic surgery; therefore, the Youm study is the best available evidence for the comparison made.

The several tables (48-59) listed for Operative Treatment of Rotator Cuff Tears, Prognostic Factor: Increasing Age, MRI characteristics, workers compensation, etc. do not include a set of tables that give information about the studies design characteristics. That needs to be added. Additionally, table 48 lists 23 studies included for increasing age. I find it hard to believe that all of them are of the same level of evidence and therefore by the rules of the guidelines they should not be included.

These tables correspond to Recommendation 7A addressing the confounding factors of age, atrophy/fatty degeneration as determined by MRI or CT scan and workers compensations status. We did use the AAOS Level of Evidence Table, Appendix V. The level of evidence for the studies supporting age and MRI tear characteristics are reported in the guideline as level IV. The study design for the included studies then were prospective case series (retrospective studies were excluded). The level of evidence supporting Worker’s Compensation status is Level II for one study and Level III for two studies. These studies were “high quality prospective studies with >80% follow-up, untreated controls from RCTs, lesser quality prospective studies with differences at baseline or with <80% follow-up, or case control studies.”

Quality tables for prognostic studies were not included because at the time this guideline was developed we did not have a quality checklist for the evaluation of prognostic studies. Since quality parameters for the evaluation of prognostic studies were not determined a priori to the literature search of the guideline, we cannot apply them at this time. As a result of improvements in our guideline development processes, we have developed quality checklists that are now embedded in a quality program for the evaluation of prognostic studies.

OVERALL ASSESSMENT

02.10
Would you recommend these guidelines for use in practice? (check one)

☐ Strongly recommend

x Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

Dear Dr. Stanwood,

We sincerely appreciate your input, time and expertise. Your comments have helped to strengthen and significantly improve the guideline we ultimately present to the AAOS Board of Directors for approval. Thank you.
American Academy of Orthopaedic Surgeons
[Optimizing the Treatment of Rotator Cuff Problems]
Guidelines Peer Review Form

ALL REVIEW COMMENTS, OUR RESPONSES AND REVIEWER COI WILL BE AVAILABLE FOR REVIEW ON OUR WEBSITE FOLLOWING BOD APPROVAL OF THIS DOCUMENT.

Review of any AAOS confidential draft allows us to improve the overall guideline but does not imply endorsement by any given individual or any specialty society who participates in our review processes. The AAOS review process may result in changes to the documents; therefore, endorsement cannot be solicited until the AAOS Board of Directors officially approves the final guideline.

Please note that if you return a review:
- Your review will be published on the AAOS website with our explanation of why we did or did not change the draft document in response to your comments
- Your conflicts of interest will be published on the AAOS website with your review

Reviewer Information:
Reg B. Wilcox III, PT, DPT, MS, OCS
Brigham & Women’s Hospital, 75 Francis Street
Boston, MA, 02054
Phone 617-732-5304
Fax 617-730-2889
E-mail rwilcox@partners.org
Specialty Area/Discipline: Physical Therapy
Work setting: Teaching Hospital
Credentials: PT, DPT, MS, OCS

May we list you as a Peer Reviewer in the final Guidelines (GL)?

X Yes  □ No

PLEASE READ: If you do not wish to be listed, your name will be removed for identification purposes. However, your review comments, our responses and your COI will still be available for public review on our website with the posted Guideline if you complete this review.

Are you reviewing this guideline as a representative of a professional society?

X Yes  □ No

If yes, may we list your society as a reviewer of this guideline?

X Yes  □ No

Society Name: American Society of Shoulder and Elbow Therapists
(Listing the specialty society as a reviewing society does not imply or otherwise indicate endorsement of this guideline.)

Conflicts of Interest (COI): All Reviewers must declare their conflicts of interest.

If the boxes below are not checked and/or the reviewer does not attach his/her conflicts of interest, the reviewer’s comments will not be addressed by the AAOS nor will the reviewer’s name or society be listed as a reviewer of this GL. If a committee reviews the guideline, only the chairperson/lead of the review must declare their relevant COI.

X I have declared my conflicts of interest on page 2 of this form.

□ I have declared my conflicts of interest in the AAOS database; my customer # is __________

X I understand that the AAOS will post my declared conflicts of interest with my comments concerning review of this guideline or technology overview on the AAOS website.
## REVIEWER CONFLICT OF INTEREST - The Orthopaedic Disclosure Program

Each item below requires an answer. Please report information for the last 12-months as required by the Accreditation Council for Continuing Medical Education (ACCME) guidelines.

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Dear Dr. Wilcox,

We appreciate your thoughtful input. In order to address your concerns, please find below a point-by-point response that has been edited and approved by the AAOS Chair and Vice-Chair of the physician work group that developed this guideline.

COMMENTS

Please provide a brief explanation of both your positive and negative answers in the preceding section. If applicable, please specify the draft page and line numbers in your comments. Please feel free to also comment on the overall structure and content of the guideline and Technical Report.

On behalf of the American Society of Shoulder and Elbow Therapists I would like to thank the American Academy of Orthopaedic Surgeons and the Guidelines Committees for inviting me to participate in the peer review of Optimizing the Management of Rotator Cuff Problems. I applaud your efforts to find evidence that supports surgical and non surgical approaches to treatment of rotator cuff injuries. I feel that the current version of the guidelines appropriately addressed most of the feedback provided from the first review by ASSET, which was provided in January 2009. I commend the committee for considering and including some of the recommend studies from our first review, particularly in the areas of exercise and manual physical therapy intervention.

Thank you.

In addition, One area that has not been addressed is:

**Statement #4 The guidelines target audience is clearly described**

In reference to line 564-570

I agree that the target audience is clearly defined however I feel it is incomplete. The list of intended users of this guideline is not a comprehensive list of healthcare providers that evaluate, assess, and advise patients with rotator cuff dysfunction. The intended users span from orthopaedic surgeons and all qualified physicians, and skips to insurance payers, governmental bodies and health policy decision-makers. Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians and physician assistants routinely see this type of patient in various practice settings.

Based on your comments, as well as the comments of others, the following text was added to the guideline at line 570:

“Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians, physician assistants and other healthcare professionals who routinely see this type of patient in various practice settings may also find this guideline useful.”

02.10  Rev 3  4
American Academy of Orthopaedic Surgeons  
[Optimizing the Treatment of Rotator Cuff Problems]  
Guidelines Peer Review Form

Dear Dr. Wilcox,

We sincerely appreciate the time, effort and expertise you have contributed to this review process. We believe your comments help strengthen the document we ultimately present to the AAOS BOD for approval. Please accept our sincerest thank-you for your input.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (check one)

☑ Strongly recommend

☐ Recommend (with provisions or alterations)

☐ Would not recommend

☐ Unsure

I would recommend these guidelines be accepted for finalization & publication. I commend the American Academy of Orthopaedic Surgeons and the Guidelines Committees for their extensive review and recommendations presented in this guideline.

I consider it an honor and a privilege to have contributed to this guideline through the peer review process. I welcome continued collaboration. Ultimately, this document and its continued development will enhance the management and the quality of care that we offer to our patients.

Dear Dr. Wilcox,

We sincerely appreciate the time and expertise you have given the Academy. Your review of both the original document and the edited document have improved the final guideline we will present to the Board of Directors. Please find below your original comments for reference.

Original Comments

On behalf of the American Society of Shoulder and Elbow Therapists we would like to thank the American Academy of Orthopaedic Surgeons and the Guidelines Committees for inviting us to participate in the peer review of Optimizing the Management of Rotator Cuff Problems. We applaud your efforts to find evidence that supports surgical and non surgical approaches to treatment of rotator cuff injuries. We hope our constructive comments will help you further refine the evidence based recommendations as well as the rational presented.
Dear Drs. Wilcox, Manske and Basti,

Thank you for all the work you have put into reviewing this guideline. We appreciate all of your thoughtful input. In order to address your comments and edits, please find below a point by point response that has been reviewed and approved by the chair and vice-chair of this guideline. Changes to the draft were made as a result of your thoughtful input and these changes improved the final document prior to sending the draft to the approval process.

**Introduction:**

Page 3, line 457. We feel this statement should be referenced.  
Referenced statements have been placed in the rewrite of the document.

Page 3, line 458. We feel this statement should be referenced.  
Referenced statements have been placed in the rewrite of the document.

Page 3, line 476. Emotional and Physical Impact of Osteoarthritis of the Knee – Is this a correct title?  
This typographical error has been edited and corrected in the rewrite of the document.

Page 7, lines 572-6. Are the comments related to “Surrogate” necessary since surrogate outcome measures are not included?  
Our opinion, as well as that of others who produce evidence-based products, is that this information may be helpful. Readers of guidelines are of varying degree of sophistication and sometimes the definitions and explanations are helpful for them.

**Statement #1: The recommendations are clearly stated**

We agree that the recommendations are clearly stated, however we feel that certain words need an operational definition and clarification such as Physical Therapy (line1745), exercise (922), activity modification (line1143, 1154,1164).  
See response to statement # 8 for further clarification.

We would define these terms based on the supporting evidence. We had no studies that referenced exercise or activity modification (Lines 922, 1143, 1154, and 1164). For physical therapy, Line 1745, the studies defined physical therapy as a form of “supervised” therapy, however the details of each program can be found in the referenced studies.

**Statement #2: There is an explicit link between the recommendations and the supporting evidence**

After a thorough review of this document we agree with most all of the evidence and rationales for each of the recommendations. However, after reading the summary of recommendations (lines 25 thru 297) without the evidence and rational accompanying the statements, it is felt that one can develop a sense of negativity when reading the
recommendations alone. Due to the subject matter and format, the document is quite large and may impede one’s ability to fully digest its full critique of the best available literature presented. We are concerned that this could possibly lead to confusion, misinterpretation, and misuse.

We agree with the reviewer’s comments, the document is large and may be cumbersome for those who only wish to skim the materials for the most salient points. The purpose of such large documents is to be transparent, and to allow readers to see exactly how we arrived at the final recommendations. Shorter, more readable versions of the guideline will be published in JAAOS and JBJS.

We add a disclaimer to encourage all readers to consult the rationales stating:
This summary does not contain rationales that explain how and why these recommendations were developed nor does it contain the evidence supporting these recommendations. All readers of this summary are strongly urged to consult the full guideline and evidence report for this information. We are confident that those who read the full guideline and evidence report will see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility. This summary of recommendations is not intended to stand alone. Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient and physician.

It is also incumbent upon the reviewer to read and understand the full depth of a recommendation to avoid confusion, misinterpretation and misuse.

We realize that identical formats have been established by the AAOS and are wondering if you have received feedback concerning this after their publication.

Yes, peer reviewers first asked for a list of summary statements and then asked that the disclaimer be made prominent by placing prior to listing the summary.

Additional concern is that readers will make an abbreviated read and bypass the rationales. Although you do state that you strongly urge the readers to consult the full guideline, our suggestion is to set the statement in a different font and/or in bold. This will help to highlight the importance of consulting the full document before it is used as a tool to aid the clinician in clinical decision-making and treatment.

We have bolded the disclaimer for clarification.

Statement #3: Given the nature of the topic and the data, all clinically important outcomes are considered:

3B - Although we understand the concern for lack of evidence regarding several treatment modalities such as iontophoresis, phonophoresis, massage, ice, and heat, we think it is reasonable that none of those modalities would, nor should be administered in isolation either during treatment or in a clinical trial. Hence, there will likely never be strong randomized trials to support or refute their use. We, in fact, believe that it may
even border being unethical in putting a patient into a research protocol to test in isolation any of these modalities. It is our experience that in all instances, these forms of modalities are done in conjunction with other forms of rehabilitation. Furthermore, we would not necessarily assume that any of these modalities in isolation will substantially have a positive or negative effect on those patients with rotator cuff tears. Clinically it appears to be a useful modality in a total treatment plan to reduce pain, improve function, and the quality of ADL. It is evident that further research is needed.

We agree and hope this guideline will spur additional high quality research to answer the questions formulated for this guideline that have no supporting evidence, including defining appropriate non-operative and post operative therapy protocols that include the modalities listed.

4F – There appears to be additional studies that indicate a positive effect of physical therapy treatment in the absence of a full thickness rotator cuff tear (impingement). We applaud your inclusion of both Bang and Walther, and would like to present the following study:


This demonstrated decreases in pain and function in both groups – self training after instruction, or by the addition of soft tissue and joint mobilization techniques. Although both groups improved, the groups that received mobilization had significantly more improvement than the self directed exercise group. These findings support that of Bang et al.

Senbursa et al. (2007) was identified by our search, reviewed and excluded from recommendation 4F. Although impingement syndrome was included in this recommendation, the workgroup agreed that outlet impingement syndrome was not equivalent to impingement syndrome and studies treating this patient population should be excluded.

**Statement #4 The guidelines target audience is clearly described**

In reference to line 413–428

We agree that the target audience is clearly defined however we feel it is incomplete. We note that the list of intended users of this guideline is not a comprehensive list of healthcare providers that evaluate, assess, and advise patients with rotator cuff dysfunction. The intended users span from orthopaedic surgeons and all qualified physicians, and skips to insurance payers, governmental bodies and health policy decision-makers. Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians and physician assistants routinely see this type of patient in various practice settings. In addition, it is
not clear who a “qualified physician” describes. Would the authors of this guideline feel that a primary care physician, primary care sports medicine physician, rheumatologist, and physiatrist be considered a qualified physician? If so, it may be clearer to the reader to list out these disciplines clearly.

Additional text has been added at line 570: “Physical therapists, occupational therapists trained in upper extremity rehabilitation, nurse practitioners, athletic trainers, primary care physicians, physician assistants and other healthcare professionals who routinely see this type of patient in various practice settings may also find this guideline useful.”

Following the review of this guideline, it is apparent that it is not intended to be a guideline for the work-up/evaluation/assessment of rotator cuff dysfunction but rather a guideline reviewing and recommending treatment options based on the best available evidence. We would recommend a statement in the introduction of this document to this effect. This would make it clearer to the reader. We trust that anyone that the authors feels falls into the ‘qualified healthcare provider’ has the basic skill set to appropriately evaluate and diagnosis rotator cuff dysfunction.

We believe we have stated the intent of the guideline in the “Goals and Rationale” section:
Line 394: The purpose of this clinical practice guideline is to help improve treatment based on the current best evidence.

Line 406: We created this guideline as an educational tool to guide qualified physicians through a series of treatment decisions in an effort to improve the quality and efficiency of care.

Statement # 5 The patients to whom this guide is meant to apply are specifically described

We agree with most of the search criteria as outlined in this guideline. It appears thorough and comprehensive for the topic at hand. However, by not including studies that looked at partial thickness tears certainly both limits the evidence that is available as well as the generalizability of this guideline to many patients seeking guidance for rotator cuff dysfunction.

We agree that the majority of the guideline is focused on patients with full-thickness tears. The Academy is constrained by time and budget requirements and must limit the focus/scope of all guidelines developed so that they remain within these constraints.

We agree that the exclusion of studies that had enrolled subjects that also had an arthroplasty, concomitant capsular release, inflammatory arthropathy, coexisting fractures, and wheelchair/weight bearing shoulder related issues is appropriate. However, this guideline does not mention either excluding or including content or studies with subjects with other concomitant pathology such as biceps dysfunction, labral tears, as
well as SLAP tears. As the authors know, many patients with shoulder pathology do not have a rotator cuff tear in isolation; hence, by not discussing recommendations for patients with the above concomitant pathology, it may significantly limit the usefulness of this guideline in clinical practice.

Based on your comments, we reviewed the 74 included studies in this guideline. Concomitant pathology such as biceps dysfunction, labral tears, as well as SLAP tears would not have been reason for exclusion; however, the majority of authors do not discuss these pathologies in their papers. We are limited by the information reported by the authors of the included studies.

**Statement # 6 The criteria used to select articles for inclusion are appropriate**
We agree. However, even though these studies were excluded from review due to the inclusion criteria used, they nonetheless influenced the rationale.

We have edited the final document to limit the inclusion of information not in the included studies. For the introductory sections of the guideline, the included studies do not address the issue of incidence, prevalence, risk factors, etc. We specifically search out additional studies that answer these informational areas. The rewritten rationales should not reference these studies however. The recommendations are now supported only by the included evidence.

Perhaps with these types of studies – i.e., studies with high level, narrowly defined inclusion criteria - maybe the inclusion criteria is too narrow and is not reporting the true picture of what is effective and is clinically recognized as effective treatment. This is perhaps an example of the inherent limitations of such strict inclusion criteria. We appreciate that the work group is eager to define best practice based on the best available evidence for clinical care, and identify gaps in science so that in the future we’ll have inclusive and higher quality research.

We agree that better high quality research is needed in the management of rotator cuff disease.

**Statement # 7 The reasons why some studies were excluded are clearly described**
We agree that is was very clear and well defined. Thank you.

**Statement # 8 All important studies that met the inclusion criteria are included:**
Recommendation 3A
Reference: lines 921-951

We feel the level of evidence for an exercise program for non-operative treatment for patients with a rotator cuff tear can further be supported with the following additional studies. We are not sure of anyone who would not attempt conservative treatment prior to surgery in the appropriate patient population. Several studies that show positive outcomes following physical therapy interventions include multiple case series such as:

This study was not identified by our searches. It was not available during our final database search in October 2008. Although this article was published in the October issue there is an unfortunate lag with databases between date of publication, date of availability and date of indexing. This is beyond AAOS control and is related to the time taken for a publisher to provide PubMed information and the time needed for PubMed to make the information available to the public. If this article meets all inclusion criteria it will be added to any future guideline updates.


Study identified, reviewed and excluded. Exclusion reason – less than 80% follow-up (see page 17 of Evidence Tables)


Study identified, reviewed and excluded. Exclusion reason – less than 80% follow-up (see pages 2, 5, & 8 of Evidence Tables)


Study identified, reviewed and excluded. Exclusion reason – less than 80% follow-up (see pages 8 & 17 of Evidence Tables)

Recommendation 4A
Reference lines 1175-1177
Several studies existing that support the positive benefit of therapeutic exercise when compared to surgery for sub-acromial impingement are:


Study identified, reviewed and excluded. Exclusion reason – A validated scale was not used by the authors (see page 36 of Evidence Tables).

This article was identified by our search, recalled and excluded. The comparison made in Haahr et al. (2005) is surgery vs. exercise. This study was not applicable to any of the recommendations asked.

Recommendation 4B
Reference lines 1204 -1225
This guideline briefly raises the point of manual therapy as an intervention for patients with rotator cuff dysfunction, by including the Bang & Deyle article, in recommendation 4B; however, the premise of this recommendation is exercise and not manual therapy. We feel that the authors of this guideline have misstated the conclusion of this article to support recommendation 4B.

We do not believe we have misstated the conclusion of this article to support Recommendation 4B. We do not report the author’s conclusions and as a matter of fact only read the methods and results sections of included studies. Our conclusions are based on the statistics reported in the study, not the discussion section of a given article or an author’s conclusions. In this trial, subjects in both groups (exercise and exercise plus manual therapy) significantly improved their “functional assessment questionnaire scores” and significantly reduced their VAS scores for pain after treatment. (see page 133 of the study).

However, the results reported between groups were “post hoc pairwise comparisons” (or a subgroup analyses after the data was collected). Based on this post hoc analyses, the author concludes that subjects with shoulder impingement syndrome who received manual therapy in addition to supervised exercise, did better in terms of strength gains, pain reduction, and functional gains than those who were given supervised exercise.

Our recommendation states:

*We suggest that patients who have rotator cuff-related symptoms in the absence of a full thickness tear be treated with an exercise program.*

The treatment comparison for this study is indicated in Table 29, page 46, and correctly indicates the comparison is “exercise with manual PT vs. exercise”. The summary table also correctly illustrates that at the final visit the results favored exercise with manual PT. For clarification and to avoid misunderstanding by other readers, we have added the following text to the rationale (bolded):

“One study23 reported on 24 patients undergoing an exercise program and noted significantly improved pain scores on the VAS [visual analog scale] after 8 weeks of treatment; *post hoc pairwise comparisons of the two groups in this study showed significantly more improvement in the exercise plus manual therapy group using a composite pain measure.*”
As stated in our disclaimer, we believe specific treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient and physician. Since the studies to support this recommendation present different exercise protocols, it is ultimately up to the individual patient and their physician to determine the best treatment plan applicable.

In addition, a few other articles exist that demonstrate better outcomes for patients, with shoulder impingement syndrome, receiving manual therapy in addition to exercise. They include:


  This article was identified, reviewed and excluded. Exclusion reason - Outlet impingement syndrome patients.


  This article is identified, reviewed and excluded. Exclusion reason - Less than 10 patients in any treatment group (see page 36 of Evidence Tables).


  This article was published after our last database search (October 6, 2008). If this guideline is updated it will be considered for inclusion at that time.

Based on the above evidence, we would recommend a separate guideline recommendation specific to the use of manual therapy in addition to exercise for patients with rotator dysfunction in the absence of a full thickness tear. This stems from the definition of manual therapy being “the application of an accurately determined and specifically directed manual force to the body, in order to improve mobility in areas that are restricted; in joints, in connective tissues or in skeletal muscles.”

Based on the Academy’s available time and budget constraints, new recommendations cannot be added following the literature search for the guideline. Again, we believe the exact exercise protocol or treatment applicable to the individual patient relies on mutual communication between patient and physician.
Recommendation 4F
Reference lines 1743 - 1783
There appear to be multiple studies that indicate a positive effect of physical therapy treatment in the absence of a full thickness rotator cuff tear (impingement). The study by Senbursa et al. demonstrated decreases in pain and function in both groups – self training after instruction or by the addition of soft tissue and joint mobilization techniques. Although both groups improved, the groups that received mobilization had significantly more improvement than the self directed exercise group.

These findings support that of Bang et al.:


This article is identified, reviewed and excluded. Exclusion reason - Outlet impingement syndrome patients.

We agree that the evidence that is available supporting the efficacy of physical therapy for patients with rotator cuff dysfunction may be inconclusive due to a dearth of high quality randomized controlled trials available for review. One major issue is that many studies do not adequately define what physical therapy interventions were, or are, included in their clinical trials. Hence, strong conclusions and the generalizability of many studies are lacking. Physical therapy can include a multitude of treatment interventions including: manual therapy, exercise, multiple local modalities, muscle reeducation, patient education, and proprioception training.

We agree. For this guideline we were bound by the definitions provided by the authors of the studies.

Thus, we recommend that both future studies and this guideline better define the interventions that constitute their operational definition of physical therapy. The term rehabilitation may be a better descriptor. In this day and age, physical therapists are not solely the ones rehabilitating patients with rotator cuff dysfunction. If we, as physical therapists, can do a better job describing and evaluating what rehabilitation protocols and interventions we are using, we will hopefully have better evidence to support, or alter, the recommendations outlined in this document in a future version.

One area that we, as physical therapists, can do a better job at in our clinical research, is specifically describing the exercise interventions that are most optimal for a given patient presentation and outcome. One specific example of an area for better description is exercise, not only the type of exercise but the frequency, duration, and specific selection of which exercises are best for a given patient presentation/diagnosis/impairment. There are many operational definitions of exercise when it comes to the shoulder. These include but are not limited to:
American Academy of Orthopaedic Surgeons
[Optimizing the Treatment of Rotator Cuff Problems]
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- Rotator cuff strengthening exercises (isometric, isotonic, isokinetic, etc…)
- Rotator cuff / joint capsule stretching exercises
- Periscapular strengthening exercises to enhance endurance, power, or better positioning of the scapula to enhance the biomechanics of the glenohumeral joint.
- General upper quarter strengthening exercises
- PROM / AAROM / AROM

Lumping evidence regarding exercise into one bucket will likely always produce inconclusive and soft evidence for its effectiveness. Certainly this is an area for physical therapists and other rehabilitation professionals to improve upon in our clinical research.

We agree and the chair of the guideline will consider your comments as he writes the “Future Research” section of this guideline.

Statement # 10 The methods are described in such a way as to be reproducible
We very much agree. Thank You.

Statement # 11 The statistical methods are appropriate to the material and objectives of this guideline
We very much agree Thank you.

Statement #12 Important parameters addressing the study result are systematically addressed
We very much agree. Thank you.

Statement # 13 Health benefits, side effects, and risks are adequately addressed
Lines 1982-90, the authors speak of high risk/low risk but do not define a base level. High risk / low risk in reference to what level of risk?

We have removed these statements from the rationales in the edited document because we are limited by time and budget constraints. These statements were based primarily in opinion and not on a formal risk analyses. Cost and risk analyses are beyond the scope of this guideline.

Lines 1155-1159, 1986-1988, 939 refer to the “cost burden” of various rehabilitation approaches, but never mentions cost with respect to conservative vs. operative treatment of rotator cuff problems. There were also no cost analysis or references cited. Perhaps the discussion of cost is not appropriate for this type of guideline. If cost is going to be mentioned, it should be considered throughout the guideline with evidence based cost analysis for all treatment mentioned in this document.

We agree. Cost and risk analyses are beyond the scope of this guideline; references to this have been deleted in the edited document, specifically at lines 3353 and 3364.
Statement # 14 The writing style is appropriate for health care professionals and Patients
It seems inconsistent that the same guideline would simultaneously be aimed at both physicians - who as defined by the criteria, have a high level of training, clinical experience, and expertise in the subject matter – and patients who’s level of knowledge can be variable and/or nonexistent. Also the format of this text does not lend itself to easy interpretation by non-clinical personnel.

We agree. The guideline is written for the healthcare professional and methodologists who wish to perform an intellectual audit of the guideline. We hope that we can prepare versions suitable for patients in the near future.

Statement # 15 The grades assigned to each recommendation are appropriate
We agree that the grades are appropriate given the amount of studies ultimately selected for the review, considering the narrow inclusion criteria.

The inclusion criteria are standard criteria accepted by the evidence based medicine community.
OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice? (Check One)

- Strongly recommend
- Recommend (with provisions or alterations)  
- Would not recommend
- Unsure

COMMENTS:
Please provide the reason(s) for your recommendation.

We would recommend these guidelines be accepted for use in clinical practice with consideration of our critique. Our critique as outlined above offers some suggestions to enhance the usefulness of this guideline. Additional literature has been provided to support the recommendations and clinical opinions of the authors where evidence is not as strong. It is our hope that this additional information may give perspective to better define some clinical definitions.

We agree. We also believe that this is a better document as a direct result of the time our volunteers donate to the advancement of evidence based medicine.

We commend the American Academy of Orthopaedic Surgeons and the Guidelines Committees for their extensive review and recommendations presented in this guideline.
We consider it an honor and a privilege to have contributed to this guideline through the peer review process. We welcome continued collaboration. Ultimately, this document and its continued development will enhance the management and the quality of care that we offer to our patients.

Thank you again for your time and expertise in reviewing this document. Your input has only served to strengthen the evidence presentation and improve the final draft that will be sent for approval.